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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,516	12/13/2006	Paola Lavermicocca	13758/1	9481

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EXAMINER	
MACAULEY, SHERIDAN R	
ART UNIT	PAPER NUMBER
1653	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,516	LAVERMICOCCA ET AL.	
	Examiner	Art Unit	
	SHERIDAN MACAULEY	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-10* is/are pending in the application.

4a) Of the above claim(s) *4,6,7,9 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A response and amendment were received and entered on September 1, 2011. All evidence and arguments have been fully considered. Claims 2 and 3 are canceled. New claims 9 and 10 are added. Claims 1 and 4-10 are pending. Claims 4, 6, 7 9 and 10 are withdrawn due to a previous requirement for restriction. Claims 1, 5 and 8 are examined on the merits in this Office action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 8 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 8 is rendered indefinite by the recitation of "in amounts sufficient of table olives to increase at least one logarithmic cycle the intestinal population of the probiotic *Lactobacillus paracasei*". It is unclear whether applicant intends to claim that the population increases one logarithmic growth cycle (i.e., a doubling) or by some other logarithmic term, such as ten-fold.

5. Thus, the metes and bounds of the claims would be unclear to one of ordinary skill in the art.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 5 and 8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Suskovic et al. (Food Technol. Biotechnol., 1997, 35:107-112; document cited in IDS) in view of Betoret (Journal of Food Engineering, 56:273-277) and Reid et al. (US

2001/0036453). The claims recite table olives characterized in that they contain probiotic lactobacilli adhering to the pericarp in an amount of 10^6 or higher bacterial cells per g of olive, or food products comprising the olives. The claims also recite that the olives contain *Lactobacillus paracasei* adhering on the pericarp in amounts sufficient to table olives to increase at least one logarithmic cycle the intestinal population of the probiotic *Lactobacillus paracasei* upon ingestion and colonization of the gastrointestinal tract.

10. Suskovic teaches olives that are prepared with probioic *Lactobacillus* spp. (abstract). The reference teaches that the olives may be used for the administration of probiotic Lactobacillus spp. to humans (abstract). The reference does not specifically teach that the cells adhere to the pericarp of the olives or the use of *Lactobacillus paracasei*.

11. Betoret teaches methods for preparing fruits in order to ensure adherence of probiotic bacteria, such as *Lactobacillus casei*, to the fruit. The reference teaches that the cells adhering to the fruit are viable and that they can contain around 10^7 CFU per g.

12. Reid teaches methods for the administration of probiotic *Lactobacillus* spp. to subjects, such as *Lactobacillus paracasei* (abstract, p. 3, par. 30-31). The reference teaches that the lactobacilli colonize the intestines of the patients (abstract, p. 2, par. 24); thus, the reference teaches that the administration of the organism results in an increase in growth of the organism in the gastrointestinal tract.

13. At the time of the invention, olives containing probiotic *Lactobacillus* spp. were known, as taught by Suskovic. It was further known that fruits containing probiotics

could be prepared to ensure adhesion of viable cells at the claimed concentrations, as taught by Betoret, and that *Lactobacillus paracasei* was a useful probiotic that is capable of colonizing the gastrointestinal tract, as taught by Reid. One of ordinary skill in the art would have been motivated to combine these teachings to arrive at the claimed composition because Suskovic teaches the desirability of administering the probiotic bacteria to a subject such that the bacteria survive to colonize the gastrointestinal tract (abstract, p. 107, col. 1) and Betoret teaches that probiotic food products should have at least 10^6 cfu per milliliter and that the methods taught therein may be used to achieve such levels (abstract, p. 273, col. 2). One of ordinary skill in the art would therefore have recognized that the methods for preparing probiotic fruits taught by Betoret could have been advantageously applied to the olives taught by Suskovic. One of ordinary skill in the art would further have been motivated to select *L. paracasei* as a bacterium for use in the preparation of olives by the combined method of Suskovic and Betoret because Suskovic teaches that lactic acid bacteria that are resistant to certain conditions in the gastrointestinal tract should be selected for use in a probiotic preparation (abstract) and Reid teaches that *L. paracasei* are advantageous lactobacilli for use in colonizing the gastrointestinal tract. One of ordinary skill in the art would therefore recognize that *L. paracasei* would be a desirable organism for use in the composition. Since the references are all directed to the preparation of a variety of food compositions comprising lactobacilli, one of ordinary skill in the art would have recognized that the methods used to prepare the similar compositions could have been combined at the time of the invention with a reasonable expectation of success. It would

therefore have been obvious to combine the cited teachings of the prior art to arrive at the claimed invention.

14. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

15. Applicant's arguments filed September 1, 2011 and May 23, 2011 have been fully considered but they are not persuasive. Applicant argues that the rejections under 35 USC 112, second paragraph have been overcome by applicant's amendment. It is noted, however, that the amendment to claim 8 did not fully address the rejection to this claim made in the previous Office action. Specifically, the claim is rendered indefinite by the recitation of "in amounts sufficient of table olives to increase at least one logarithmic cycle the intestinal population of the probiotic *Lactobacillus paracasei*". It is unclear whether applicant intends to claim that the population increases one logarithmic growth cycle (i.e., a doubling) or by some other logarithmic term, such as ten-fold. The amendment made to the claim did not address this issue; thus, the claim stands rejected under 35 USC 112, second paragraph.

16. Applicant also argues that the claims are not rendered obvious in view of the cited prior art because the references do not teach or suggest that the lactobacilli can adhere to the pericarp of olives in amounts sufficient to provide a probiotic nutritional benefit. This is not found to be persuasive, however, because the references teach that olives containing lactobacilli are known in the art, that lactobacilli can be adhered to

fruits in the claimed numbers, and that the administered lactobacilli can proliferate in the intestinal tract. For the reasons set forth above, it would have been obvious to one of ordinary skill in the art to prepare a table olive meeting the claimed limitations. Although applicant argues that the Suskovic reference does not specifically teach olives that have been prepared for probiotic purposes, it is noted that the reference teaches that the lactobacilli may be combined with the olives; the use of lactobacilli for probiotic purposes is taught by the Betoret and Reid references. Although applicant also argues that the Betoret reference is directed to the adherence of lactobacilli to dried fruit and not to brine-soaked olives, it is noted that the claims do not recite brine-soaked olives, and thus do not preclude the preparation method recited by Betoret. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Although applicant also argues that one of ordinary skill in the art would not have had a reasonable expectation of success in preparing the claimed invention in view of the cited prior art, this is not found to be persuasive because the preparation of lactobacilli-containing olives was known in the art, as was the preparation and administration of lactobacilli in foods. One of ordinary skill in the art would recognize that the amount of lactobacilli in the olives could have been modified using the methods of Betoret with a reasonable expectation of success. Thus, the claims are rendered obvious in view of the cited prior art.

17. Applicant also argues that the claimed invention provides unexpected results, in that the lactobacilli adhere to the pericarp of the olive in numbers that provide a specific

probiotic effect in the intestinal tract. This is not found to be persuasive, however, because it was known in the art at the time of the invention that fruits could be prepared containing the claimed amount of adherent probiotic lactobacilli, and that such probiotics can exert the claimed effect on the gastrointestinal tract. Thus, one of ordinary skill in the art would not have been surprised by the results contained in the specification. Therefore, applicant's arguments have not been found to be persuasive.

18. Thus, applicant's arguments have been fully considered, but they have not been found to be persuasive.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sue Liu can be reached on (571) 272-5539. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM
/Ruth A. Davis/
Primary Examiner, Art Unit 1651